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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,621	02/19/2002	Peng Cho Tang	038602-1325	2320

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WASHINGTON, DC 20007

EXAMINER

STOCKTON, LAURA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER
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DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on January 15, 2003

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-17 are pending in the application.  
Of the above, claim(s) 1-4, 7-12 and 14-17 are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 5, 6 and 13 (all in-part) are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892  
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

## DETAILED ACTION

**Claims 1-17 are pending in the application.**

### *Election/Restrictions*

Applicants' election with traverse of Group III in Paper No. 7 and the species of the first compound found in Table 2 on page 99 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that: (1) the restriction is improper with respect to Groups III, IV and V; (2) sufficient evidence to demonstrate serious burden has not been provided; and (3) method claims should be rejoined if the composition claims are found patentable.

All of Applicants' arguments have been considered but have not been found persuasive. The restriction between Groups III, IV and V is proper for reasons given in the restriction requirement on pages 3 and 4. Further, separate search considerations (not just classification) are involved for each of the groups listed which would impose an undue burden on the Examiner and the Patent Office's resources if unrestricted.

The rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper.

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

The generic concept that has been examined, inclusive of the elected species (the first compound found in Table 2 on page 99), is as follows:

3-[(indole-3-yl)methylene]-2-indolinone compounds (see specifically instant claim 6) wherein

R<sub>1</sub> is an unsubstituted alkyl;

$R_2$ ,  $R_3$ ,  $R_4$ ,  $R_5$  and  $R_6$  are each hydrogen;

$R_7$ ,  $R_8$ ,  $R_9$  and  $R_{10}$  are each hydrogen.

Claims, in-part, embraced by the generic concept are claims 5, 6 and 13.

The requirement is still deemed proper and is therefore made  
FINAL.

Subject matter not embraced by the above identified generic concept and claims 1-4, 7-12 and 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

It is suggested that in order to advance prosecution, the non-elected subject matter be cancelled when responding to this Office Action.

*Information Disclosure Statement*

Applicants stated that copies of the references listed on the 1449 form filed August 8, 2002 {Paper No. 5} could be found in parent applications 09/617,529 and 08/915,366. However, upon review of the parent applications, only a few of these references were found in these parent applications. Therefore, only US Patents and those references found in the parent applications have been considered. Those references that have been considered have only been considered to the extent of the scope of the above identified generic concept.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C.

112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, Applicants are claiming in claim 6 “a metabolite of the compounds”. The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The instant specification does not give any guidance as to what is meant by “a metabolite of the compound”. The instant specification does not give any guidance as to how “a metabolite of the compound” is made. In order to practice the claimed invention, one skilled in the art would have to speculate on Applicants’ intended meaning. The number of possible radicals embraced by the claims would impose undue experimentation on the skilled art worker. Therefore, the terminology “a metabolite” is not enabled because the metes and bounds of the claims cannot be ascertained.



The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 lacks antecedent basis from claim 5 since it is not stated in claim 5 that the compound could be in the form of a "salt, isomer, metabolite, ester, amide or prodrug thereof". Claim 6 is indefinite because Applicants' intended meaning of "a metabolite of the compound" is not taught or disclosed.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 6 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by:

a) von Dobeneck et al. {CA 71:3203, 1969} – see the compound of CA Registry No. 22813-84-9;

b) Heath et al. {WO 95/17181} – see the compound on page 9, line 21 and the compositions taught on pages 12-14; and

c) Buzzetti et al. {WO 93/01182} – see the compound on page 20, line 8 and the compositions taught on pages 13-15.

Each of the above cited references disclose 3-[(1'-methyl-3'-indolyl)methylen]-2-oxindole {CA Reg. No. 22813-84-9}, which is Applicants' elected species (the first compound found in Table 2 on page 99).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heath et al. {WO 95/17181} and Buzzetti et al. {WO 93/01182}, each taken alone.

***Determination of the scope and content of the prior art (MPEP §2141.01)***

Applicants claim 3-[1'-unsubstituted alkyl-(indole-3-yl)methylene]-2-indolinone products. Heath et al. (pages 2, 3 and 11-14; or the compound on page 9, line 21) and Buzzetti et al. (pages 1, 2 and 13-15; or the compound on page 20, line 8) each teach 3-[1'-unsubstituted alkyl-(indole-3-yl)methylene]-2-indolinone products that are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed products.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between some of the products of the prior art and the products instantly claimed is that of generic description.

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., angiogenesis inhibitors).

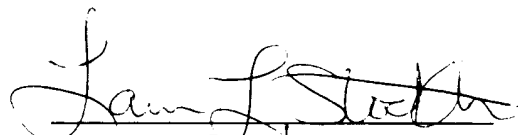
One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, inflammation. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

The elected species, the first compound found in Table 2 on page 99, is not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

A handwritten signature in cursive script, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

May 5, 2003